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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/940,377	08/27/2001	Gust H. Bardy	032580.0006.UTL	5562

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EXAMINER	
DROESCH, KRISTEN L	
ART UNIT	**PAPER NUMBER**
3762	

DATE MAILED: 05/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/940,377	BARDY ET AL.	
	Examiner	Art Unit	
	Kristen L Droesch	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *3/17/04 (response)*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20,22-88,90-95 and 97-110* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-20, 22-31, 63- 88, 90-95 and 97-110* is/are allowed.

6)☐ Claim(s) *32-52,55,56 and 58-62* is/are rejected.

7)☐ Claim(s) *53,54 and 57* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/17/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The indicated allowability of claims 32-62 is withdrawn in view of the newly discovered reference(s) to the anatomical location of the third rib (23) in the Sanchez–Zambrano reference (5,895,414). Rejections based on the newly cited reference(s) follow.

Election/Restrictions

2. Applicant's election without traverse of Species VII in Paper No. 8 is acknowledged.

3. Claims 1, and 63 are generic and allowable. Accordingly, the restriction requirement as to the encompassed species is hereby withdrawn and claims 13-17, and 75-79, directed to non-elected are no longer withdrawn from consideration since all of the claims to this species depend from or otherwise include each of the limitations of an allowed generic claim.

In view of the above noted withdrawal of the restriction requirement as to the linked species, applicant(s) are advised that if any claim(s) depending from or including all the limitations of the allowable generic linking claim(s) be presented in a continuation or divisional application, such claims may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 32-46, 49-50, 52, 56, and 58-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bardy (5,292,338) in view of Meltzer (5,645,586) and further in view of Sanchez-Zambrano (5,895,414).

Regarding claim 32, Bardy shows a method of inserting an implantable cardioverter defibrillator comprising providing an ICD canister, making an incision into the patient (Abs) and

advancing the ICD canister through the incision and subcutaneously over the patient's ribcage in the area defined between approximately a patient's third and twelfth rib. (Abs; Col. 3, line 57-Col. 4, line12). Although Bardy fails to specifically state that the ICD is implanted between the third and twelfth rib, Sanchez-Zambrano shows the pectoral implant region is below the clavicle (21) and the third rib (23) (Fig. 2), thus between the third and twelfth rib.

Although Bardy fails to teach that the ICD canister is non-planar to maintain the cardioverter in a predetermined relationship with to a patient's heart, over the patient's ribcage, attention is directed to Meltzer which teaches an ICD canister that is adapted to follow the contours of the pectoral region of the patient's body either by a flexible housing or hinges. Meltzer teaches that this modification minimizes skin dislocation, protrusions, irritation, medical complications, obtrusiveness, and patient discomfort (Col. 1, line 38-Col. 2, line 2).

Although Bardy and Meltzer fail to teach that the ICD canister is non-planar, attention is directed to Sanchez-Zambrano which teaches a pacemaker housing (canister) that is non-planar and addresses the same deficiencies that the Meltzer device addresses. Sanchez-Zambrano teaches that the pacemaker housing is contoured to the natural curvature of the patient's ribs to fit smoothly under the skin and against the ribcage (Col. 1, lines 22-26), thereby avoiding the discomfort, unsightly bulges, and high stress zones on the skin of the prior art (Col. 1, lines 11-18).

Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the method of Bardy with a conformable ICD canister of Meltzer in order minimize skin dislocation, protrusions, irritation, medical complications, obtrusiveness, and patient discomfort, and further it would have been obvious to one with ordinary skill in the

art at the time the invention was made to modify the method of Bardy modified with the ICD canister of Meltzer with an canister that is non-planar and contoured to the natural curvature of the patient's ribs to fit smoothly under the skin and against the ribcage as Sanchez-Zambrano teaches in order to avoid discomfort, unsightly bulges, and high stress zones on the skin.

Regarding claims 33-39, Bardy, Meltzer, and Sanchez-Zambrano disclose the claimed invention except for the specific dimensions of the housing. It would have been an obvious matter of design choice to size the length of the canister less than 30 cm, approximately 3 cm to 30 cm long, approximately 5 cm to 20 cm long, or approximately 5 cm to 12 cm long, the width of the canister to be approximately 3 cm to 10 cm wide, or approximately 3 cm to 6cm wide, and the depth of the canister to be less than 15 mm since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 UPSQ 237 (CCPA 1955).

With respect to claim 40, Bardy, Meltzer, and Sanchez-Zambrano show the canister comprises a first end and a second end (Fig. 1 of Bardy, Fig. 2 of Meltzer, Fig. 1 of Sanchez-Zambrano).

Regarding claim 41, Bardy and Meltzer show the width of the canister between the first and second end are substantially similar (Fig. 1 of Bardy, Fig. 2 of Meltzer).

With respect to claim 42, Meltzer shows a length of the canister is greater than a width of the canister (Fig. 2).

Regarding claim 43, Bardy shows a length of the canister is substantially similar to a width of the canister (Fig. 1).

With respect to claim 44-46, Bardy shows the first end (top) and the second end (bottom) of the ICD is rounded (the corner edges) and the second end (bottom) is substantially square (Fig. 1).

Regarding claim 49, Bardy shows the ICD comprises at least a portion that is substantially non-planar (the corner edges) (Fig. 1).

With respect to claims 50, Bardy shows the ICD comprises an electrical circuit (Fig. 2) located within a portion of the ICD (Abs).

Regarding claim 52, Bardy shows a portion of the canister comprises an electrically insulated material (Col. 3, lines 46-57).

With respect to claims 56, and 58, Bardy, shows the canister is advanced proximate a patient's heart and sternum.

Regarding claims 59-60, Bardy, Meltzer, and Sanchez-Zambrano show the canister refrains from directly contacting the patient's heart or intrathoracic vasculature (Fig. 1 of Bardy, Fig. 12 of Meltzer, Figs 4-7 of Sanchez-Zambrano).

With respect to claims 61-62, Meltzer shows the length of the defibrillator is oriented along the length of the ribs (Figs. 1, 5) and Bardy shows the length of the defibrillator is oriented perpendicularly to the length of the ribs (Fig. 1).

6. Claim 47-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bardy (5,292,338) in view of Meltzer (5,645,586) and Sanchez-Zambrano (5,895,414) as applied to claim 32 and further in view or Adams (5,601,607). Bardy, Meltzer, and Sanchez-Zambrano disclose the claimed invention except for the ICD having a width that tapers inwardly between the second end and the first end of the ICD, or a depth that decreases from the second end of the

ICD to the first end of the ICD. Adams shows an ICD having a width that tapers inwardly between the second end and the first end of the ICD, and a depth that decreases from the second end to the first end of the ICD (Figs. 7-8). It would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to modify the shape of the ICD as taught by Bardy, Meltzer, and Sanchez-Zambrano with an ICD having a width that tapers inwardly between the second end and first end of the ICD, and a depth that decreases from the second end to the first end of the ICD, as Adams teaches since applicant has not disclosed that the tapering width or decreasing depth of the housing provides any criticality and /or unexpected results and it appears that the invention would perform equally well with any shape housing taught by Bardy Meltzer, and Sanchez-Zambrano for applying defibrillation energy. A change in shape absent persuasive evidence of the significance of the configuration has been held to be a matter of obvious design choice to one with ordinary skill in the art. See *In re Dailey,* 357 F.2d 669 (CCPA 1966).

7. Claims 51 is are rejected under 35 U.S.C. 103(a) as being unpatentable over Bardy (5,292,338) in view of Meltzer (5,645;586) and Sanchez-Zambrano (5,895,414) as applied to claim 32 and further in view of Mower (5,871,506). Bardy, Meltzer, and Sanchez-Zambrano disclose the claimed invention except for the setting forth the specific waveforms utilized in cardiac pacing. Mower teaches using biphasic (i.e. multiphasic) waveforms for cardiac pacing in order to improve cardiac conduction and contraction (Col. 2, lines 42-53). Therefore it would have been obvious to one with ordinary skill in the art at the time the invention was made to apply biphasic (i.e. multiphasic) pacing pulses as Mower teaches with the device of Bardy,

Meltzer, and Sanchez-Zambrano since they are well known in the art and the application of biphasic pulses provides the advantage of improving cardiac conduction and contraction.

8. Claim 55 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bardy (5,292,338) in view of Meltzer (5,645,586) and Sanchez-Zambrano (5,895,414) as applied to claims 32. Bardy, Meltzer, and Sanchez-Zambrano are as explained before. Although Bardy, Meltzer, and Sanchez-Zambrano fail to specifically show a step of shaping a passageway within the patient for the ICD to navigate, it is well known in the art that ICD's are implanted in surgically formed passageways (pockets) in the chest. Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to shape a passageway within the patient for the ICD to navigate since it is well known. See for example Alt (6,076,014; Col. 4, lines 55-57) and Kroll (6,169,923; Col. 4, lines 13-15).

Allowable Subject Matter

9. Claims 1-20, 22-31, 63-88, 90-95, 97-110 are allowed. See paper No. 9.

10. Claims 53-54 and 57 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

With respect to claim 53, the prior art of record fails to teach or suggest a method of inserting an ICD comprising providing an ICD having an electrode located on the housing and configured to provide a shocking energy to the patient's heart by the electrode; making an incision into the patient; advancing the ICD through the incision and subcutaneously in the area defined between approximately a patient's third and twelfth ribs in combination with the incision being made approximately at the level of the cardiac apex.

Regarding claim 54, the prior art of record fails to teach or suggest a method of inserting an ICD comprising providing an ICD having an electrode located on the housing and configured to provide a shocking energy to the patient's heart by the electrode; making an incision into the patient; advancing the ICD through the incision and subcutaneously in the area defined between approximately a patient's third and twelfth ribs in combination with the incision being made approximately in the left anterior axillary line.

With respect to claim 55, the prior art of record fails to teach or suggest a method of inserting an ICD comprising providing an ICD having an electrode located on the housing and configured to provide a shocking energy to the patient's heart by the electrode; making an incision into the patient; advancing the ICD through the incision and subcutaneously in the area defined between approximately a patient's third and twelfth ribs in combination with the ICD being advanced medially toward a patient's left inframamary crease.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen L Droesch whose telephone number is 703-605-1185. The examiner can normally be reached on M-F, 10:00 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angie Sykes can be reached on 703-308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

kld

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